REMARKS

Claim 1 is directed to a non-reactive pressure sensitive adhesive composition comprising an acrylic polymer and a therapeutic agent. Claim 1 has been amended to limit the therapeutic agent to a non-salt agent. Support for the foregoing amendment is replete throughout the application, and may be found for instance in pages 14-15 which includes various active agents in its basic form.

Claim 12 has been amended to recite the therapeutic agent is fentanyl. Support for the foregoing amended is replete throughout the application, and may be found for instance in page 14, line 20.

Claim 22 has also been amended to limit the therapeutic agent to a non-salt agent. Support for the foregoing amendment is replete throughout the application, and may be found for instance in pages 14-15 which includes various active agents in its basic form.

No new matter has been added. Entry is requested. Accordingly, upon entry hereof, claims 1, 3-7, 9-16, 17-19 and 21-23 will be under consideration or reconsideration.

Applicants turn to the substance of the Action, in which rejections have been advanced against the pending claims under 35 U.S.C. §§ 102 and103.

Rejection under 35 U.S.C. § 102

Claims 1, 3-7, 9-14, 18, 19, 21, 22 are rejected under 35 U.S.C. § 102(b) as being anticipated by Nakagawa et al. (JP 61-126020, hereinafter "Nakagawa").

Nakagawa discloses a patch for external use that contains amfenac sodium (sodium (2-amino-3-benzoylphenyl)acetate monohydrate) as its active ingredient in an acrylic adhesive (page 117, right column, second paragraph and page 118, left column, fifth paragraph).

Although Applicants do not agree, solely in order to expedite prosecution of the present application, claim 1 has been amended to limit the therapeutic agent to a non-salt agent. Claims 4-7, 10 and 18-19 depend from the amended claim 1. In order for a reference to anticipate, the reference must disclose all the elements of the claim within the four corners of the document, and must also disclose those elements arranged as in the claim. Nakagawa fails to disclose all of the Applicants' claimed elements within the four corners of the document and in the combination claimed by Applicants and, as such, fails to anticipate the claimed invention. Nakagawa fails to disclose that the therapeutic agent is a non-salt. As amended, claim 1 requires that the non-reactive pressure sensitive adhesive composition contains a therapeutic agent that is not in the form of a salt. Reconsideration and withdrawal of the Section 102 rejections of claims 1, 4-7, 10 and 18-19 is therefore respectfully requested.

Again, although Applicants do not agree, solely in order to expedite prosecution of the present application, claim 12 has been amended to limit the therapeutic agent to fentanyl. Claims 13, 14, 16, 17, 19, 21 depend from claim 12. In order for a reference to anticipate, the reference must disclose all the elements of the claim within the four corners of the document, and must also disclose those elements arranged as in the claim. Nakagawa fails to disclose fentanyl as the therapeutic agent, and as such, fails to anticipate the claimed invention. Reconsideration and withdrawal of the Section 102 rejections of claims 12-14, 16-17, 19 and 21 is therefore respectfully requested.

In order to expedite prosecution of the present application, claim 22 has been amended to limit the therapeutic agent to a non-salt agent. Nakagawa fails to disclose that the therapeutic agent is a non-salt. Reconsideration and withdrawal of the Section 102 rejections of claims 1 is

therefore respectfully requested.

Rejection under 35 U.S.C. § 103

Claims 3 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Nakagawa in view of Akemi (EP 0531938, hereinafter "EP'938").

Applicants disagree.

To establish a *prima facie* case of obviousness, there must be some reason, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the references or to combine reference teachings. *KSR International Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007). Moreover, the cited reference must teach or suggest all the claim limitations, and a reasonable expectation of success must be found elsewhere than in Applicants' disclosure. That is, the claim recitations must be found in the cited reference, the nature of the problem to be solved, or in the knowledge/understanding of the person of ordinary skill in the art. MPEP § 2143; *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). Here, Nakagawa in view of EP'938 does not support a *prima facie* case of obviousness.

As an initial matter, Applicants ask for clarification of the statement regarding paragraph 7 on page 7 of the Office Action dated October 21, 2010. The Examiner urges that EP'938 recognizes the equivalency between monomer having an amide bond taught by Nakagawa and (meth)acrylonitrile as suitable polymer to polymerize with alkyl(meth)acrylate monomer.

EP'938 is directed to a reactive pressure sensitive adhesive formed using an acrylic ester-based polymer and a liquid component and then crosslinking the polymer to allow it to gel. The resultant pressure sensitive adhesive has a good balance of adhesion to the skin and skin-unstimulating properties (EP'938, page 2, lines 54-56). Particularly, it is taught that obtaining

acrylic ester-based polymers by an alkyl (meth)acrylate and at least one carboxyl group-containing monomer and hydroxyl group-containing monomer, as essential components, controls the amount of crosslinking sites and tackiness properties (EP'938, page 4, lines 33-37). Thus, crosslinking the polymer is essential to EP'938. While EP'938 teaches that alkyl (meth)acrylate is copolymerized with other various monomers, the alkyl(meth)acrylate must still further react (and crosslink) with at least one carboxyl group-containing monomer and hydroxyl group-containing monomer.

Unlike EP'938, the instant invention is directed to a non-reactive pressure sensitive adhesive that specifically lacks carboxyl groups and hydroxyl group containing monomers. As such, a skilled artisan would not look to EP'938 to develop a non-reactive pressure sensitive adhesive that does not require any post-polymerization chemical crosslinking.

There is no teaching, suggestion or motivation to combine the teachings of Nakagawa and EP'938. Nakagawa is directed to a particular active, specifically, amfenac sodium (sodium (2-amino-3-benzoylphenyl)acetate monohydrate), in an acrylic adhesive system. EP'938 is directed to a reactive pressure sensitive adhesive formed by crosslinking the polymer to allow it to gel. As such, the invention of claim 3 would not have been obvious to one of ordinary skill in the art from the disclosures of Nakagawa in view of EP'938r. Withdrawal is requested.

Claims 15-17 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Nakagawa in view of Miranda et al. (US 5,474,783, hereinafter "Miranda").

Applicants disagree.

The arguments set forth above related to Nakagawa are equally applicable here. Nakagawa teaches that preparation of percutaneous absorption of anti-inflammatory and

analgesic agents have historically been unsuccessful because they had a low bioavailability (paragraph bridging pages 117-118). Nakagawa, thus, teaches that the "percutaneous absorption occurs efficiently in the case in which a patch containing this drug in the adhesive is applied to the skin. This efficient percutaneous absorption is manifested only when one of the acrylic adhesives presented below is used as the adhesive" (page 118, paragraph bridging two columns). Clearly, Nakagawa is directed to efficient percutaneous absorption of one particular active, namely, amfenac sodium (sodium (2-amino-3-benzoylphenyl)acetate monohydrate), in an adhesive. Nowhere is there any suggestion that a different active, let alone fentanyl, could have efficient percutaneous absorption on the skin.

Miranda, as a secondary reference, fails to cure the defect of Nakagawa so as to render obvious the claimed invention. Miranada is directed to a blend of at least two polymers having differing solubility parameters, and the blend requires both polyacrylate and a polysiloxane (column 3, lines 36-40 and column 4, lines 6-10). While the passage cited by the Examiner (Office Action dated October 21, 2010, Paragraph 8, page 9, citing Miranda, column 9, lines 21-59), points to the acrylic potion of Miranda's adhesive, Miranda, as a whole, also requires polysiloxane as a polymer component. Miranda teaches that the combination of polyacrylate and polysiloxane forms as a mutually interpenetrating polymeric network, which results in acceptable shear, tack and peel properties (column 9, lines 4-20).

As such, the invention of claims 15-17 would not have been obvious to one of ordinary skill in the art from the disclosures of Nakagawa in view of Miranda. There is no teaching, suggestion or motivation to combine Nakagawa and Miranda to arrive at the instant invention, which specifically requires fentanyl without a mutually interpenetrating polymeric network

which additionally requires polysiloxane. Withdrawal is requested.

Claims 23 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Nakagawa.

Applicants disagree.

Again, Nakagawa teaches the discovery of an efficient percutaneous absorption for amfenac sodium (sodium (2-amino-3-benzoylphenyl)acetate monohydrate) in an acrylic adhesive. Nowhere is there any suggestion that a different active, let alone a non-salt, could have efficient percutaneous absorption on the skin. As such, the invention of claim 23 would not have been obvious to one of ordinary skill in the art from the disclosures of Nakagawa. Withdrawal is requested.

Conclusion

Applicants believe that the foregoing constitutes a complete and full response to the Office Action. Accordingly, an early and favorable reconsideration of the rejections and an allowance of all of pending claims are earnestly solicited.

Respectfully submitted,

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